

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

REMARKS

In the Office Action, claims 11-14, and 16-18 are rejected under 35 U.S.C. § 102(b); claims 11, 12, 16-19 and 21, 23 and 24 are rejected under 35 U.S.C. § 103(a); and claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. § 103(a). Claims 11, 19 and 23 have been amended to further clarify the present invention. Applicants respectfully submit that the rejections have been overcome or are improper for the reasons set forth below.

In the Office Action, claims 11-14 and 16-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,494,664 (“the ‘664 Patent”). The Patent Office essentially asserts that the ‘664 Patent discloses each and every feature of the claimed invention. Applicants believe that the anticipation rejection is improper.

The sole independent claims, claims 11, 19 and 23 provide a method for the treatment or prophylaxis of calcium deficiencies in a mammal having a calcium deficiency or at risk of having a calcium deficiency (Claim 11); a method for increasing absorption of calcium from a diet in a mammal requiring increased calcium absorption (Claim 19); and a method for improving the absorption of calcium in a mammal requiring increased calcium absorption (Claim 23).

The ‘664 Patent discloses administering a strain of bacteria to human beings or animals as an antidiarrhoeic. The ‘664 Patent fails to disclose a method for the treatment or prophylaxis of calcium deficiencies, a method for increasing absorption of calcium from a diet, or a method for improving the absorption of calcium. In fact, this reference fails to disclose mineral absorption in general. The Patent Office, however, contends that because the ‘664 Patent discloses the use of the *Lactobacillus acidophilus* strain as an antidiarrhoeic, any use of lactobacillus related to “improving mammal health” is inherent. The ‘664 Patent, however, fails to disclose administering the claimed nutritional composition to a mammal having a calcium deficiency or at risk of having a calcium deficiency or in a mammal requiring increased calcium absorption as required by the claimed invention. Therefore, Applicants respectfully submit that the ‘664 Patent is deficient with respect to the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejections with respect to the claimed invention be withdrawn.

In the Office Action, claims 11, 12, 16-19 and 21, 23 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the publication by *Sellars*, R. L., “Acidophilus Products” (“*Sellars*”) and the publication by *Yaeshima*, T., “Benefits of Bifidobacteria to Human Health” (“*Yaeshima*”). Applicants respectfully submit that *Sellars* and *Yaeshima* are deficient with respect to the now claimed invention.

Independent claims 11, 19 and 23 have been amended and now each include, in part, the step of administering to the mammal a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal wherein the nutritional composition is not a fermented nutritional composition. Support for these amendments can be found in the Specification, page 5, lines 23-27. There is nothing inherently ambiguous or uncertain about a negative limitation when alternative elements are positively recited in the specification but explicitly excluded in the claims. See MPEP§2173.05(i).

The Patent Office relies on *Sellars* and *Yaeshima* to support the fact that it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use live lactic bacteria of the genus *Lactobacillus* to increase calcium absorption. See Office Action at page 5.

Among the health promoting properties associated with the establishment of the acidophilus species of the *Lactobacillus* genus in the microflora disclosed by *Sellars* is the increase in mineral absorption. However, *Sellars* teaches on page 102, paragraph 2, lines 1-4, “that when fermented dairy products containing lactobacilli are consumed, the bioavailability for mineral absorption is increased”. (emphasis added). Moreover, *Sellars* teaches that it is the metabolite of a fermented dairy product, lactic acid, which influences the rate of absorbed minerals. See *Sellars* page 102, paragraph 2, lines 4-5 and lines 15-17. Therefore, the increased mineral absorption taught in *Sellars* is limited to fermented dairy products containing lactobacilli.

The Patent Office admits that *Sellars* does not teach the absorption of the mineral calcium and relies on *Yaeshima* to teach the method for treatment and/or improving absorption of a mineral that is calcium. However, *Yaeshima* fails to teach or suggest the use of *Lactobacillus* bacteria to improve calcium absorption. Rather, *Yaeshima* discloses the use of *Bifidobacterium longum* (*B. longum*) in combination with the oligosaccharide, lactulose, which “promotes whey

Ca absorption and thereby increases the strength of bone. *See Yaeshima*, page 41, column 2, paragraph 1, lines 2-5 and *See Figure 13*. In this regard, *Yaeshima*, at most, discloses a lactulose-dependent effect on calcium absorption.

The Patent Office attempts to cure the deficiency that *Yaeshima* fails to teach or suggest the use of *Lactobacillus* bacteria to improve calcium absorption by characterizing *Bifidobacterium* as “representative of ‘lactobacilli’ contained in ‘acidophilus’ products.” *See Office Action*, page 5, paragraph 2. It appears that the Patent Office uses Tables I, II and III in *Sellars* to make this characterization. Although various species of the *Bifidobacteria* genus are present in some of the acidophilus products which include *acidophilus* species of lactobacilli as disclosed in *Sellars*, the bifidobacteria are merely adjunct microflora in addition to acidophilus and presumably different from acidophilus bacteria. *See Sellars* page 83, paragraph 3, lines 7-9, and *see* the heading for the fourth column in each Table I-III, pages 84-86. The Patent Office also bases its characterization of bifidobacteria on the general statement in *Yaeshima* that *Bifidobacterium* and *Lactobacilli* are typical examples of beneficial bacteria. Bifidobacteria and lactobacilli, however, are completely different bacteria from completely different phyla.

One of skill in the art would not be motivated to administer lactobacilli to treat or prophylax calcium deficiency because bifidobacteria, as alleged by the Patent Office to be representative of the whole group of beneficial bacteria, is regarded as being beneficial for mineral absorption including calcium absorption. *Yaeshima*, in fact, clearly teaches away from the use of lactobacilli to assist in digestion and absorption as illustrated in Figure 1 of *Yaeshima* (see below). Figure 1 lists lactobacilli as one of several genera of bacteria in the intestinal flora. Unlike bifidobacteria, however, lactobacilli is shown to only prevent colonization of pathogens and stimulation of immune response as the beneficial effect on the host. The figure fails to connect lactobacilli with assisting in digestion and absorption as is bifidobacteria. Therefore, one of skill in the art would not be motivated to administer lactobacilli to treat or prophylax calcium deficiency, and *Sellars* and *Yaeshima* are deficient in disclosing each and every element of the claimed invention.

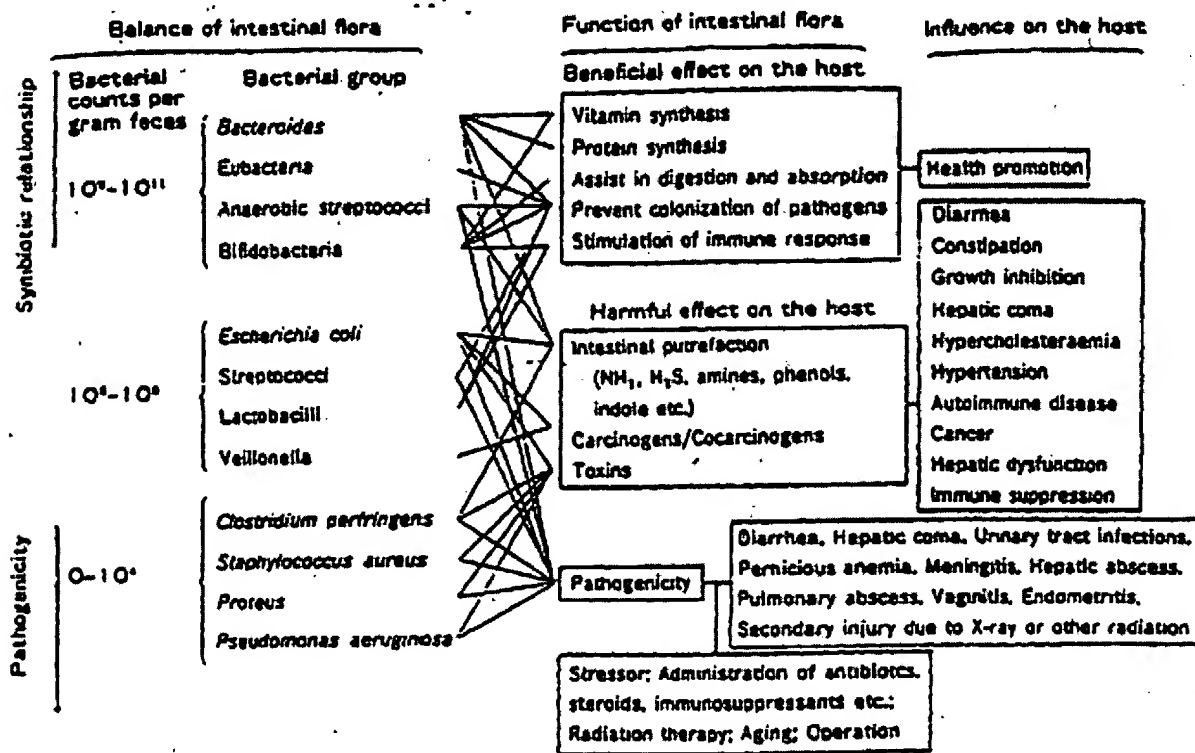


Figure 1: Interrelationships between intestinal flora and the human body [1].

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. §103 as being unpatentable over *Sellars* and *Yaeshima* as applied to claims 11, 12, 16-19, 21, 23 and 24 and further in view of U.S. Patent No. 5,578,302 ("the '302 Patent") and the '664 Patent. The Patent Office primarily relies on the *Sellars* and *Yaeshima* and, thus, relies on the combined teachings of the '302 Patent and the '664 Patent to remedy the deficiencies of the *Sellars* and *Yaeshima*. Applicants respectfully submit that this rejection is improper for the reasons set forth below.

As discussed above, the *Sellars* and *Yaeshima* references alone or in combination fail to disclose a method for the treatment or prophylaxis of calcium deficiencies in a mammal having a calcium deficiency or at risk of having a calcium deficiency (Claim 11); a method for increasing absorption of calcium from a diet (Claim 19); and a method for improving the absorption of calcium in a mammal (Claim 23), wherein each of the methods include, in part, the step of administering to the mammal a nutritional composition that includes one or more *Lactobacillus*

bacteria capable of arriving in a living state in intestines of the mammal wherein the nutritional composition is not a fermented nutritional composition.

Like the '664 *Patent*, the '302 *patent* primarily relates to an agent (anti-gastritis and/or anti-ulcer agent) which displaces pathogenic bacteria from intestinal and/or gastric cells to treat a physical condition of the GI tract. Moreover, the '302 *patent* is not directed to a mammal having a calcium deficiency or at risk of having a calcium deficiency or a mammal requiring increased calcium absorption as required by the claimed invention. See the '302 *Patent*, Col. 1, lines 34-36. Therefore, the '664 *Patent* and the '302 *patent* fail to cure the deficiencies of the combined teachings of *Sellars* and *Yaeshima*. Thus, one skilled in the art, viewing the combined teaching of the secondary references, would not be inclined to modify the primary references, alone or in combination, to arrive at the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,
BELL, BOYD & LLOYD LLC

By 

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

Dated: February 4, 2004